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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/025,196	12/18/2001	Christopher C. Lawrence	9793/102	6395

7590 04/19/2004

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EXAMINER	
CEPERLEY, MARY	
ART UNIT	**PAPER NUMBER**
1641	

DATE MAILED: 04/19/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/025,196	LAWRENCE ET AL.	
	Examiner	Art Unit	
	Mary (Molly) E. Ceperley	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-34* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-34* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *09/17/2002*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

1) The application serial numbers missing on pages 1, 11 and 16 of the specification must be supplied.

2) A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

3) Claims 1-34 are rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1034 of prior U.S. Patent No. 10/053,058. This is a double patenting rejection.

4) Although specific claims are cited in the rejections below, these rejections are also applicable to all other claims in which the noted problems/language occur.

5) The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6) Claims 1-15 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for "treating said sensitized particles in an aqueous mixture with an amine compound" wherein the treatment results in the *reaction of* the "succinimide ester groups" with the amine functionality of the "amine compound" *to form an amide linkage* as set forth at page 9, lines 13-17

of the specification, does not reasonably provide enablement for "treating" wherein no such reaction occurs. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

7) Claims 16-34 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the preparation of a "sensitized particle" wherein the "at least one antibody" is bound to the surface by reaction of the NHS/CDI-activated carboxylate groups on the particle surface with an amine group on the antibody (claims 16, 29 and 30), does not reasonably provide enablement for an antibody bound to the surface through *any/all* types of "covalent bond". The invention described in the specification is directed specifically to NHS/CDI-activated carboxylate groups which are used to attach *both* the antibody and the amine compound to the particles. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. The specification is also enabling only for the case in which the "succinimide ester" is *covalently attached* to the particle surface. The claim 16 term "the reaction product of a succinimide ester and an amine compound of formula (I) on the surface" does not require such an attachment; this term includes the case wherein the "reaction product" is simply coated on the surface.

8) The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9) Claims 1-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over each of Dijksma et al (Anal. Chem., 73(5), 901-907 [2001]) or Inzana (J. Clin. Microbiol., 33, 2297-2303 [1995]).

The references describe a conventional method of attaching a ligand (antibody) to a particle utilizing a carbodiimide/succinimide (CDI/NHS) activation of carboxylate groups on the particle, the same method described in instant claim 1. See Dijksma et al: abstract; page 902, last paragraph; page 903, « Chemicals »; Inzana : page 2298, « Preparation of SLP » ; abstract. The references describe the further addition of ethanolamine to deactivate residual succinimide groups on the particle surface. This step corresponds with the step of "treating said sensitized particles in an aqueous mixture with an amine compound of formula (I)" of instant claim 1. See Dijksma et al: abstract; page 907, « Immobilization of MD-2 Antibodies »; Inzana: "Preparation of SLP", page 2298. The structure of the succinimide deactivator ethanolamine (prior art) corresponds to the structure of the succinimide deactivator of formula (I) of instant claim 1 wherein R = ***2***, X = -OH. However, the proviso of instant claim 1 limits R to the range of "***4*** to 20 carbon atoms". See Dijksma et al: abstract; page 907, « Immobilization of MD-2 Antibodies »; Inzana: "Preparation of SLP", page 2298.

Given the teachings of the prior art, i.e. that ethanolamine is a known deactivating agent for residual succinimido groups present after CDI/NHS coupling of a ligand to a carboxylated particle, it would be obvious to substitute other well known homologs of ethanolamine [$HO\text{-}(CH_2)_{\mathbf{2}}\text{-}NH_2$], for example $HO\text{-}(CH_2)_{\mathbf{4}}\text{-}NH_2$, in the method of either Dijksma et al or Inzana, as claimed, with the expectation of obtaining a similarly useful succinimido deactivation method which produces particles useful in immunoassays. For a discussion of similar utilities to be expected for structurally similar compounds (homologs) see MPEP 2144.09.

For the use of BSA as a conventional blocking agent (instant claim 29), see Inzana, page 2298, "Immunological assays".

The features of the dependent claims are either specifically described by the references (e.g. for a pH of at least 7.0 of instant claim 7, see Inzana, page 2298, "Immunological assays") or constitute obvious variations in parameters which are routinely modified in the art (e.g. varying ratios of reactants) and which have not been described as critical to the practice of the invention.

The packaging of reagents in kit form (instant claim 34) is an obvious expedient for ease and convenience in assay performance.

10) Claims 1-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over DADE BEHRING (WO98/36277) taken in combination with the admitted prior art as set forth at page 1, line 27 through page 2, line 17 of the instant specification.

The instant specification establishes that CDI/NHS (succinimide) mediated linkage of antibodies to carboxylated particles is well known in the art and that it is also well known that residual succinimide (NHS) esters remain on the particles after the reaction. This is the methodology used in instant claim 1.

DADE BEHRING establishes that compounds of the type recited in instant claim 1, formula (I) wherein X =-OH and R = alkyl ether, are well known stabilizers for immunoassay particles which contain succinimidyl (NHS) ester groups. See DADE BEHRING: page 4, lines 12-33; page 6, lines 31-33; claim 13.

Given the fact that amine- and hydroxy-substituted alkyl ethers are well known stabilizers for particles containing residual succinimidyl (NHS) ester groups (DADE-BEHRING), it would be obvious to use these stabilizers for particles containing the same residual succinimidyl (NHS) ester groups present as a byproduct of using conventional NHS (succinimide)/CDI linking methodology (admitted prior art), as claimed.

The features of the dependent claims are either specifically described by the references or constitute obvious variations in parameters which are routinely modified in the art (e.g. varying ratios of reactants) and which have not been described as critical to the practice of the invention.

The packaging of reagents in kit form (instant claim 34) is an obvious expedient for ease and convenience in assay performance.

11) An inquiry of a general nature which is ***not related to the prosecution on the merits*** should be directed to Technology Center 1600 telephone number (571) 272-1600. The general fax number for the USPTO is (703) 872-9306.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary (Molly) E. Ceperley whose telephone number is (571) 272-0813. The examiner can normally be reached from 8 a.m. to 4:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le, can be reached on (571) 272-0823.

April 14, 2004

Mary E. Ceperley

Mary (Molly) E. Ceperley
Primary Examiner
Art Unit 1641